GENWORKS HEALTH PRIVATE LIMITED

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No. 14629

TECHNICAL SERVICE REPORT

CALL DETAILS		SERVICE STATUS	INSTRUMENT DETAILS	SITE CONDITION
	DATE	☐ WARRANTY	MODEL : Ions	L&N VOLT : 230V
CALL REGD.	14/06/22	☐ R & R		N&E VOLT : 2V
RESPONSE	14/06/22	☑ AMC	SR. NO :	L&E VOLT : 228V
CALL COMPLETE	14/6/22	☐ CMC	1606216	
		☐ C & C		
		☐ BREAKDOWN		

CUSTOMER NAME : Vello poonawala Hospital

ADDRESS : Hadapsar, Pune

AMC/WARRANTY PERIOD

FROM ..... TO .....

PROBLEM REPORTED : Calibration Report for electrolyte Analyser.

PROBLEM OBSERVED : Ions electrolyte Analyser is being self calibrate it own automatically after each 8 hours.

ACTION TAKEN : Herewith certified that, Ions electrolyte Analyser is self calibrate it own automatically after each 8- hour.

FOLLOW UP ACTION (if necessary) : NA

SPARE PARTS : ☐ APPROVAL ☐ REPLACED

NO.	DESCRIPTION	QTY.	COST	TOTAL
	NA	NA		NA

ENGINEER / PRODUCT SPECIALIST : Service Engineer

SIGNATURE : Nathwa

NAME : NHin Phadatare

DATE : 14/06/2022

CUSTOMER FEEDBACK : Machine working satisfactory.

CUSTOMER NAME : Vello Poonawala Hosp.

SIGNATURE :

NAME : Dr. Vaishali Jain

DATE : 14/06/2022

Dr. VAISHALI JAIN
MBBS, MD (Patho.)
Reg. No:- 2004/02/831
Vello Medical Foundation's
Vilioo Poonawalla Memorial Hospital

NOTE :

1. Parts replaced are chargeable except during warranty period
2. Parts replaced due to negligence will also be charged in every case
3. Consumables are not covered by warranty period

Regd. Off : Unit 522-524, 5th floor Gamma block, Sigma soft tech park Bangalore-560066, **TOLL FREE : +91 80 46667766**
E-mail : gwsocallcentre@genworkshealth.com

Caretium

Reagent consumption data list

We, Caretium Medical Instruments Co., Limited, orginal manufacuturer of XI921/ Volton Electrolyte analyzer serie,here confirm the below consumption for XI921/ Volton Electrolyte analyzer series is true:

1. Calibration (turn on the machine) : A solution: 1.6ml
   B solution: 1.0 ml

- Calibration(wake up in half of hour): A solution: 0.13ml
- Calibration (wake up after half of hour): total volume: 2.8ml
  - A solution: 1.6ml
  - B solution: 1.2 ml
- Per Test : A solution: 0.4ml , B solution: 0 ml(one point calibration)

Chen Jian
Senior Service Director
Caretium Medical Instruments Co., Limited

CARETIUM MEDICAL INSTRUMENTS CO.,LIMITED
Beishan Industrial Park 7th Floor Building 1, Beishan Road, Yantian, Shenzhen 518083 China
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GEN WORKS

A WIPRO GE HEALTHCARE INVESTED COMPANY

INSTALLATION QUALIFICATION

Instrument Name : IONS F ELECTROLYTE ANALYZER

Laboratory/Hospital: Welfare Medical Foundation Villoo Poonawala Memorial Hospital

Supported By : Genworks Health Pvt Ltd,

INSTALLATION QUALIFICATION PROTOCOL

This Installation Qualification Protocol is performed in the site located at

The purpose of this installation qualification protocol is to define the qualifications and the acceptance standard in order to verify that instrument installation, normal operation and function of the Ions F Electrolyte analyzer in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- Genworks Health Pvt. Ltd. is responsible for installation of Ions F Electrolyte analyzer at Welfare Medical Foundation Villoo Poonawala Memorial Hospital as per the attached protocol.
- An authorized representative of Genworks Health Pvt. Ltd. will physically check the system and proceed for the installation.
- This installation protocol will be followed as specified by the manufacturer. Installation checks will also be performed to verify that the instrument has been installed with proper connections and utilities.
- On completion of the Installation all the necessary documents of system checks will be used to evaluate the instrument installation in accordance with the manufacturer's protocol and intended use.
- Successful completion of this protocol will verify that this instrument has been installed in accordance with the intended usage.

- Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated, and appropriate course of action will be determined.
- The results of these installation activities are the base for the subsequent Operational & Performance Qualification Protocol.

REPORT SIGN OFF:

Protocol Prepared By

Designated Company Person Name: Nitin Phadtare

Designation: Service Engineer

Date: 13/04/2022

Protocol Prepared For

Customer / Contact Person Name: Dr Vaishali

Hospital / Institution: Welfare Medical Foundation Villoo Poonawala Memorial Hospital

Equipment Information:-

Equipment Name: Ions F Electrolyte Analyzer

Model/Type: XI-921BT

Serial No: 1606216

Equipment Installed Location: Pathology Laboratory

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A WIPRO GE HEALTHCARE INVESTED COMPANY

Installation Date: 17/10/2016

INSTRUMENT INSTALLATION QUALIFICATION PROTOCOL

Ions F Electrolyte Analyzer has been found to be satisfactorily installed at laboratory department and has complied to the installation requirement based on the below described items.

Installation Requirements:-

Space Requirement:-

- The instrument should be installed on a stable and solid platform that is free of mechanical vibration and away from vibration source.

Environment Requirement:-

- Working environment: 15°C - 32°C
- Relative humidity: <85%
- Atmospheric pressure: 76kPa~106kPa
- The environment should be dust free, and away from corrosive gas, loud noises and electrical interference.
- Do not put the analyzer in the vicinity of brush motor, flicker fluorescent tube and other constant on-off electrical equipment.

- Avoid direct sunlight and do not place the analyzer in front of heat source and wind source.

Power Requirement:-

- The power supply should be AC220/110V 10%, 50/60Hz 1Hz
- Power supply and grounding should be connected correctly.

Verify the Pre-installation Checks:-

If any deficiencies are noted during the pre-installation check, they should be verified and resolved before installation.

Check the Supplies:-

Make sure there is adequate supply of materials available at the site for installation.

Inspect Packing Box:-

Inspect all boxes for damage. Notify shipper of damages if any.

Unpack the Analyzer:-

- Remove the packing material of the Analyzer.
- Place the Instrument on the cabinet or table.
- Check accessories refer to the packing list, contact supplier immediately if there is any damage or missing parts.
- Check instrument name and model code.

Installation of New Electrodes:-

- Verify electrode assembly and check for visibly good condition.
- Check if the filling solutions are sufficient.
- Installed electrode assembly to electrode holder.

Installation of the reagent:-

- Take off rubber cap of external reagents; connect tubes according to outlet marks.
- Finally, check out the whole tubing system.

Installation of the Printer paper:-

- Insert the paper support on the stand.
- Insert the paper into the guide slot.
- Make sure the thermal side of the paper faces downward.
- Pull up the lever on the right, rotate the knob until the paper comes out and then push the lever down.

Installation Information:-

Name of the Instrument: Ions F Electrolyte Analyzer

Physical Verification of the instrument before installation: Satisfactory

Description of the equipment along with the components: Reagent, printer paper and accessories.

Date of Installation: 17/10/2016

Name of Engineer (S): Mr. Nitin Phadtare

Installation conclusion:-

Overall instrument installation requirements were found to be satisfactory and hence handed over the instrument for operation & performance qualification.

Installation Certificate: Enclosed

Installation Protocol Remarks: Action to be taken (if any):

Reports Sign Off:-

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A WIPRO GE HEALTHCARE INVESTED COMPANY

Designated Person Name: Nitin Phadtare

Laboratory Personal Name: Dr Vaishali

Designation: Service Engineer

Designation: Pathologists

Signature:

Signature:

Date: _____

Date: _____

Attachments:

1. Instrument Installation certificate

GEN WORKS

A WIPRO GE HEALTHCARE INVESTED COMPANY

OPERATIONAL QUALIFICATION

Instrument Name : IONS F ELECTROLYTE ANALYZER

Laboratory/Hospital : Welfare Medical Foundation Villoo Poonawala Memorial Hospital

Supported By : Genworks Health Pvt Ltd,

OPERATION QUALIFICATION PROTOCOL

This Operation Qualification Protocol is performed in the site located at

The purpose of this operation qualification protocol is to define the qualifications and the acceptance standard in order to verify the normal operation and function of the Ions F Electrolyte analyzer in the laboratory. The satisfactory outcome of this procedure assures that the system functions according to the parameters.

- This protocol defines the documentation that will be used to evaluate the instrument and documented in accordance with manufacturer's specifications and intended use.
- Successful completion of this protocol will verify that the instrumentation identified has been operational in accordance with manufacturer's specifications and intended use.
- Operational checks will be performed to verify that the instrument operates according to specifications and to record the information/data to demonstrate its functions as expected.
- Trained knowledgeable personnel from Genworks Health Pvt. Ltd. along with the department personnel will perform qualification studies as mentioned by the manufacturer.
- Any exceptional conditions encountered during the qualification studies will be identified for review and documented in deviation report. Exceptional conditions will be investigated, and appropriate course of action will be determined.
- The results of that installation activity are the base for the subsequent of Operational Qualification Protocol.
- The operational qualification protocol will verify the review of the start-up procedure,

- Operation processes, instrument routine maintenance, instrument safety handling in the laboratory.

REPORT SIGN OFF:

Protocol Prepared By

Designated Company Person Name: Mr. Nitin Phadtare

Designation: Service Engineer

Date: 13/04/2022

Protocol Prepared For

Customer / Contact Person Name: Dr. Vaishali

Hospital / Institution: Welfare Medical Foundation Villoo Poonawala Memorial Hospital

Equipment Information:-

Equipment Name: Ions F Electrolyte Analyzer

Model/Type: XI-921BT

Serial No: 1606216

Equipment Installed Location: Clinical Laboratory

Installation Date: 17/10/2016

OPERATIONAL QUALIFICATION PROTOCOL

1. OPERATION QUALIFICATION PROCEDURES

1.1 Start-up & Self-test:-

☐ After the instrument has been correctly installed, turn on the power and boot up the instrument, the instrument carries out the self-test for the positioner, printer and auto sampler.

- When the initialization finishes successfully, the sample probe comes down, and a few seconds later, the screen displays: Measure ISE STD,,,,,,
- It indicates the instrument is carrying out calibration. The system checks the positioner' voltage, pump pulse numbers and electrode potential.
- When the calibration is completed, the screen displays respective electrode slopes values and the results will also be printed out.
- After the calibration, the screen will display the main menu.

1.2 Instrument Operation Qualification Detailed Information:-

- Input supply and lamp voltage for the machine was found adequate using the multimeter.
- Instrument tubing systems check found to be satisfactory
- Reagents systems check, sampling ,STD A & STD B checks found to be satisfactory.
- Electrode assembly system verification found to be satisfactory.
- Mixing chamber working condition found to be satisfactory.
- Instrument components check also found to be satisfactory.

1.3 Preliminary Operation

Carry out the maintenance procedures	:	yes
If necessary, check the analyzer parts mechanical movements:		yes
Check the reagent flow and peristaltic pump movement	:	yes
Check the STD slope values	:	yes
Carry out routine test by manual mode	:	yes
Check Result verification	:	yes

1.4 Parameter Setup

- Date and Time Setting : dd/mm/yyyy
- Language setup : yes
- On screen-keyboard : yes
- Printer setting : yes

1.5 Instrument Safety and Environmental Condition

- Check the room temperature : Yes
- Check the humidity : Yes
- Check the environmental condition : Yes
- Ensured the symbol of biohazard : Yes
- Ensured controls & reagents solution usage and storage instruction: Yes
- Check the waste disposal requirement : Yes

1.6 1.5 Instrument Operation and Routine Maintenance Training:-

- Instrument operation, user instrument maintenance and training undergone by all the laboratory personals : Yes
- Individual training certificate enclosed : Yes

Operation Qualification Conclusion:-

With the reference to the instrument operation procedure and studies carried out in the laboratory, the Ions F Electrolyte Analyzer meets all criteria outlined as per manufacturer recommended protocols.

Overall instrument installation requirements found to be satisfactory. Instrument handed over for performance qualification.

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Installation Protocol Remarks: Action to be taken (if any):

Reports Sign Off:-

Designated Person Name: Mr Nitin Phadtare Laboratory Personal Name: Dr Vaishali

Designation: Service Engineer Designation: Pathologists

Signature: Signature:

Date: Date:

Attachments:

1. Calibration and Control value & results sheets
2. Slope value print out

GEN WORKS

A WIPRO GE HEALTHCARE INVESTED COMPANY

PERFORMANCE QUALIFICATION

Instrument Name : **IONS F ELECTROLYTE ANALYZER**

Laboratory/Hospital : Welfare Medical Foundation Villoo Poonawala Memorial Hospital

Supported By : Genworks Health Pvt Ltd,

INSTRUMENT PERFORMANCE QUALIFICATION PROTOCOL

1. PERFORMANCE QUALIFICATION PROCEDURES

- Following Procedure was Carried out as part of the Performance Qualification:-

1.1 Control measurement:

The main function for Quality Control system is to examine the accuracy for sample analysis through the test for blood sample controls and the collection for QC data.

The aim for QC include the accurate and repeatability for test results.

Prepare the QC liquid according to the requirements in the QC instruction.

QC Conclusion: Control recoveries found to be within the limits.

Note: Attached controls reports.

1.2 QC result verification

- Check the appropriate control level results : yes

1.3 Performance Qualification Procedures

- Run respective controls materials with appropriate levels at known concentration to check the test items accuracy.
- Carry out 10 replicates (between run) for each level of control or pooled serum samples for appropriate parameters & calculate the coefficient of variance.
- Comparison correlation with appropriate patient test result.

1. Measure ISE, STD & slope results verification.

Test Items	Obtained Slopes Results	Normal Range of the Slopes
Na	57.7	27 – 70 mV/dec
K	56.4	27 – 70 mV/dec
Cl	47.1	20 – 70 mV/dec

2. Run the controls materials to verify the recoveries & performance monitoring within the clinical range.

3. Between run repeatability & within run repeatability.
   i. Biorad Control Level 1 Repeatability data

Test Items	Assay Mode	No of Replication	Mean	SD	CV%
Na	ISE	10	147.2	0.57	0.37
K	ISE	10	4.01	0.01	0.34
Cl	ISE	10	103.0	0.60	0.58

   ii. Ions QC solution Repeatability data

Test Items	Assay Mode	No of Replication	Mean	SD	CV%
Na	ISE	3	147.5	0.32	0.22
K	ISE	3	4.87	0.02	0.44
Cl	ISE	3	103.3	0.21	0.21

- Perform the reproducibility check by running the patient samples 10 times and verify the CV% is within the limits specified.
- Perform accuracy check by running normal and abnormal controls 10 times and verify whether the %CV, bias and %bias is within the specified limits.

Performance Qualification Conclusion:-

The controls results are obtained as per specifications & tolerance ranges. Verified that the calibration & controls results according to the specific limits and determined that the results were satisfactory. Herewith certificate that Ions F Electrolyte Analyzer operates correctly according to the instrument specifications.

With the reference to the installation, operation & performance procedures and studies carried out in the laboratory, Ions F Electrolyte Analyzer meets all criteria outlined for respective protocol.

User operation & maintenance, and hands-on training was given to all the respective technical personal in the laboratory in accordance to the protocol.

Performance Protocol Remarks: Action to be taken (if any):

Reports Sign Off:-

Designated Person Name: Mr Nitin Phadtare Laboratory Personal Name: Dr Vaishali

Designation: Service Engineer Designation: Pathologists

Signature: Signature:

Date: 14/06/2022 Date: 14/06/2022

Attachments:

1. Calibration and control results raw data
2. Repeatability check data
3. User operation and training certificate

TIME: 2022-06-14 13:55
QC
Lot No: 0000000000020210222
K 4.89 mmol/L
Na 146.1 mmol/L
Cl 102.0 mmol/L

TIME: 2022-06-14 13:56
QC
Lot No: 0000000000020210222
K 4.83 mmol/L
Na 147.9 mmol/L
Cl 103.6 mmol/L

TIME: 2022-06-14 13:57
QC
Lot No: 0000000000020210222
K 4.91 mmol/L
Na 148.5 mmol/L
Cl 104.3 mmol/L